



I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

On \_\_\_\_\_

TOWNSEND and TOWNSEND and CREW LLP

By: \_\_\_\_\_

Attorney Docket No. 015280-212200US

*Suppl. Decl. #13 (unsigned)*  
PATENT  
*6. 11.03*

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Salahuddin *et al.*

Application No.: 10/087,882

Filed: March 1, 2002

For: ANTIBODIES AGAINST HUMAN  
HERPES VIRUS-6 (HHV-6) AND  
METHOD OF USE

SECOND SUPPLEMENTAL REISSUE  
DECLARATION UNDER 37 C.F.R. §  
1.175(a)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

We, Syed Z. Salahuddin, Dharam V. Ablashi, Steven F. Josephs, Carl W. Saxinger,  
Flossie Wong-Staal and Robert C. Gallo, declare as follows:

1. We are citizens and residents of the United States of America.

2. We have assigned the entire right, title, and interest in U.S. Patent No. 6,054,283 to the United States of America as represented by the Secretary of the Department of Health and Human Services.

3. We are the original inventors of the invention described and claimed in the above-identified United States Letters Patent and the claims added by the above referenced reissue application, for which invention we seek a reissue of the aforesaid Letters Patent.

4. We do not know and do not believe that the invention was ever known or used in the United States of America before our invention thereof.

5. We have reviewed and understand the contents of the amended claims as presented in the accompanying response to the Office Action mailed on March 5, 2003 for the above-referenced application.

6. We acknowledge the duty to disclose information of which we are aware and which is material to the examination of this application for reissue of the original Letters Patent in accordance with 37 C.F.R. § 1.56.

7. We believe the original patent to be partly inoperative in that the original patent claims less than we have a right to claim in the patent. Our invention is generally directed to methods of detecting human B lymphotropic virus (HBLV) infection. Claims 2 and 3 of the issued patent recite two distinct methods by which HBLV infection can be detected. Claim 2 describes a method of detecting HBLV infection by contacting an antibody that specifically binds to an antigenic molecule from HBLV with a biological sample and detecting the antibody-antigen complex. Claim 3 describes a method whereby the antibody-antigen complex is detected by a western blot.

The methods recited in claims 2 and 3 are not the only methods of detecting HBLV infection. For example, HBLV infection can be detected by immunoassays that detect antibodies that specifically bind to HBLV as described at column 10, lines 59-67 and column 13, lines 3-6 of U.S. Patent No. 6,054,283.

8. We believe that the unduly constrained literal scope of the claims prior to this amendment arose from insufficient communication between us and patent counsel as a result of which the patent counsel lacked full appreciation of the scope and function of the invention. <sup>AKA</sup> (These errors in claiming less than we had a right to claim arose without any deceptive intention on our part.)

9. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full name of first inventor: Syed Z. Salahuddin

Inventor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Country of Citizenship: U.S.

Residence: U.S.

Post Office Address: \_\_\_\_\_

Full name of second inventor: Dharam V. Ablashi

Inventor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Country of Citizenship: U.S.

Residence: U.S.

Post Office Address: \_\_\_\_\_

Full name of third inventor: Steven F. Josephs

Inventor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Country of Citizenship: U.S.

Residence: U.S.

Post Office Address: \_\_\_\_\_

Full name of fourth inventor: Carl W. Saxinger

Inventor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Country of Citizenship: U.S.

Residence: U.S.

Post Office Address: \_\_\_\_\_

Full name of fifth inventor: Flossie Wong-Staal

Inventor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Country of Citizenship: U.S.

Residence: U.S.

Post Office Address: \_\_\_\_\_

Full name of sixth inventor: Robert C. Gallo

Inventor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Country of Citizenship: U.S.

Residence: U.S.

Post Office Address: \_\_\_\_\_

**PATENT**  
Attorney Docket No. 015280-212200US

#13  
Decl. (unsigned)  
6.1.03

TOWNSEND and TOWNSEND and CREW LLP

By: \_\_\_\_\_

Salahuddin *et al.*

**SUPPLEMENTAL REISSUE  
DECLARATION UNDER 37 C.F.R. §  
1.175(a)**

For: ANTIBODIES AGAINST HUMAN  
HERPES VIRUS-6 (HHV-6) AND  
METHOD OF USE

Sir:

1. We are citizens and residents of the United States of America.

2. We have assigned the entire right, title, and interest in U.S. Patent No. 6,054,283 to the United States of America as represented by the Secretary of the Department of Health and Human Services.

3. We are the original inventors of the invention described and claimed in the above-identified United States Letters Patent and the claims added by the above referenced reissue application, for which invention we seek a reissue of the aforesaid Letters Patent.

4. We do not know and do not believe that the invention was ever known or used in the United States of America before our invention thereof.

5. We have reviewed and understand the contents of the amended claims as presented in the response filed on February 6, 2003 for the above-referenced application.

6. We acknowledge the duty to disclose information of which we are aware and which is material to the examination of this application for reissue of the original Letters Patent in accordance with 37 C.F.R. § 1.56.

7. We believe the original patent to be partly inoperative in that the original patent claims less than we have a right to claim in the patent. Our invention is generally directed to methods of detecting human B lymphotropic virus (HBLV) infection. Claims 2 and 3 of the issued patent recite two distinct methods by which HBLV infection can be detected. Claim 2 describes a method of detecting HBLV infection by contacting an antibody that specifically binds to an antigenic molecule from HBLV with a biological sample and detecting the antibody-antigen complex. Claim 3 describes a method whereby the antibody-antigen complex is detected by a western blot.

The methods recited in claims 2 and 3 are not the only methods of detecting HBLV infection. For example, HBLV infection can be detected by immunoassays that detect antibodies that specifically bind to HBLV as described at column 10, lines 59-67 and column 13, lines 3-6 of U.S. Patent No. 6,054,283.

8. We believe that the unduly constrained literal scope of the claims prior to this amendment arose from insufficient communication between us and patent counsel as a result of which the patent counsel lacked full appreciation of the scope and function of the invention. These errors in claiming less than we had a right to claim arose without any deceptive intention on our part.

9. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full name of first inventor: Syed Z. Salahuddin

Inventor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Country of Citizenship: U.S.

Residence: U.S.

Post Office Address: \_\_\_\_\_

Full name of second inventor: Dharam V. Ablashi

Inventor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Country of Citizenship: U.S.

Residence: U.S.

Post Office Address: \_\_\_\_\_

Full name of third inventor: Steven F. Josephs

Inventor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Country of Citizenship: U.S.

Residence: U.S.

Post Office Address: \_\_\_\_\_

Full name of fourth inventor: Carl W. Saxinger

Inventor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Country of Citizenship: U.S.

Residence: U.S.

Post Office Address: \_\_\_\_\_

Full name of fifth inventor: Flossie Wong-Staal

Inventor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Country of Citizenship: U.S.

Residence: U.S.

Post Office Address: \_\_\_\_\_

Full name of sixth inventor: Robert C. Gallo

Inventor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Country of Citizenship: U.S.

Residence: U.S.

Post Office Address: \_\_\_\_\_